

**REMARKS**

Claims 1 and 3-5 are pending. By this Amendment, Claims 1 and 3-5 are amended merely for cosmetic purposes and in no way are the amendments made thereto intended to overcome any applied art of record or any reasons related to patentability thereof. As such, Applicant respectfully submits no new material is presented herein.

**Claim Rejections – 35 U.S.C. §112**

Claims 1 and 3-5 are rejected under 35 U.S.C. §112, second paragraph. Applicant respectfully traverses the rejection.

The Office Action notes page 8, lines 9-13 of the Specification states the presence of the deformable elements enables the valve to operate in immediate fashion, opening it and closing it in very short time intervals. However, the Office Action asserts that on pages 7-8, the disclosure of the operation of the apparatus does not appear to convey “a plurality of deformable connecting elements between the ring and shutter to allow said shutter to move from said operative blocking configuration to said operative configuration of consent and vice versa” as claimed in Claim 1. The Office Action further asserts there does not appear to be a functional relationship disclosed between the shutter and deformable elements. Thus, the Office Action concludes that the operation of the apparatus, as disclosed on pages 7-8, does not seem to comply with that which is being claimed.

Applicant respectfully disagrees with the assertions made by the Office Action as the Specification provides an enabling disclosure of that which is claimed.

In particular, Applicant respectfully points out that paragraphs [0028] through [0031], i.e., page 5, line 13 to page 6, line 13 of the originally filed application, states:

[0028] The nebuliser ampoule 2 is provided with a first opening 4 for aspirating air from the environment, during the inspiration phase, and with a second opening 5 for expelling air into the environment, during the expiration phase. The apparatus 1 comprises a valve 6 for regulating a flow of air entering the nebuliser ampoule 2. This valve is positioned in correspondence with the aforesaid opening 4 necessary to aspirate air from the environment and it is preferably associated to a so-called supplementary, or secondary, channel 7 of the nebuliser ampoule.

[0029] The flow regulating valve 6 is of the type comprising a shutter 8 able to move between an operative blocking configuration corresponding to an obstruction of the opening 4 (as shown in FIG. 1) and an operative configuration corresponding to an obstruction of the opening 5 (as shown in FIG. 1) and an operative configuration (not shown herein) of consent to the passage of the flow of air.

[0030] ***The shutter 8 is anchored to a tubular portion 2a of the nebuliser ampoule 2 by means of a ring 9 connected to the shutter by means of a plurality of deformable elements 10 which elements, given their deformability, allow the shutter 8 to move from the operative blocking configuration to the operative consent configuration and vice versa.*** In particular, said movement is directly caused by the vacuum generated on the shutter 8 by the user. In the illustrated embodiment, the deformable elements 10 are spiral shaped and have a first end fastened peripherally to the shutter 8 and a second end fastened to the ring 9.

[0031] The shutter 8, the ring 9 and the deformable elements 10 are preferably obtained in a single body and are made of polymeric material, typically rubber. (emphasis added)

As such, Applicant respectfully submits the originally filed application provides a clear description of how the plurality of deformable elements (10), which are illustrated in Figures 1 and 3, are disposed between the ring (9) and the shutter (8) to allow the shutter (8) to move between the two configurations. Moreover, the above-quoted passages also clearly provide the functional relationship between the shutter (8) and deformable elements (10).

In view of the above, Applicant respectfully requests withdrawal of the rejection.

### Specification

The Office Action objects to the Specification for lacking an adequate explanation of how the shutter (8) moves back to a resting position. Applicant respectfully traverses the objection. Applicant respectfully points out that paragraphs [0028] through [0031], i.e., page 5, line 13 to page 6, line 13 of the originally filed application, states:

[0028] The nebuliser ampoule 2 is provided with a first opening 4 for aspirating air from the environment, during the inspiration phase, and with a second opening 5 for expelling air into the environment, during the expiration phase. The apparatus 1 comprises a valve 6 for regulating a flow of air entering the nebuliser ampoule 2. This valve is positioned in correspondence with the aforesaid opening 4 necessary to aspirate air from the environment and it is preferably associated to a so-called supplementary, or secondary, channel 7 of the nebuliser ampoule.

[0029] The flow regulating valve 6 is of the type comprising a shutter 8 able to move between an operative blocking configuration corresponding to an obstruction of the opening 4 (as shown in FIG. 1) and an operative configuration corresponding to an obstruction of the opening 4 (as shown in FIG. 1) and an operative configuration (not shown herein) of consent to the passage of the flow of air.

[0030] ***The shutter 8 is anchored to a tubular portion 2a of the nebuliser ampoule 2 by means of a ring 9 connected to the shutter by means of a plurality of deformable elements 10 which elements, given their deformability, allow the shutter 8 to move from the operative blocking configuration to the operative consent configuration and vice versa.*** In particular, said movement is directly caused by the vacuum generated on the shutter 8 by the user. In the illustrated embodiment, the deformable elements 10 are spiral shaped and have a first end fastened peripherally to the shutter 8 and a second end fastened to the ring 9.

[0031] The shutter 8, the ring 9 and the deformable elements 10 are preferably obtained in a single body and are made of polymeric material, typically rubber. (emphasis added)

As such, Applicant respectfully submits the originally filed application provides a clear description of how the shutter (8) moves between the two, i.e., resting and non-resting, positions. In view of the above, Applicant respectfully requests withdrawal of the objection.

**Claim Objections**

Claim 1 is objected to for an informality therein. The claim has been amended responsive to the objection. Withdrawal of the objection is respectfully requested.


**Conclusion**

In view of the foregoing, reconsideration of the application, withdrawal of the outstanding objection and rejection, allowance of Claims 1 and 3-5, and the prompt issuance of a Notice of Allowability are respectfully solicited.

Should the Examiner believe anything further is desirable in order to place this application in better condition for allowance, the Examiner is requested to contact the undersigned at the telephone number listed below.

In the event that the filing of this paper is not deemed timely, Applicant petitions for an appropriate extension of time. Any petition fee for the extension of time and any other fees that may be required in relation to this paper can be charged to Deposit Account No. 01-2300, **referencing Docket No. 024931-00026.**

Respectfully submitted,

  
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